

### **REMARKS**

After entry of this amendment, claims 1, 4, 7, 9, 11-17 and 26-30 are pending, of which claim 27 is withdrawn. Claim 10 has been cancelled without prejudice or disclaimer. New claims 28-30 have been added and find support *inter alia* in the original claim 1. New claim 29 finds further support in the specification, for example, at page 24, lines 15-18. The claims have been amended without prejudice or disclaimer and find support *inter alia* in the original claims. Claim 1 finds further support in the specification, for example, at page 24, lines 15-18. No new matter has been added.

### **Claim Rejection – 35 U.S.C. § 112**

Claims 1, 4, 7, and 9-17 are rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of an enabling disclosure. Applicants respectfully disagree and note the inconsistent treatment given by the Examiner to the cited Guo reference and the Board's decision in *Ex parte Sun*. While maintaining the applicability of Guo in supporting the present rejection even though Guo deals with different proteins, the Examiner contends that *Ex parte Sun* does not apply here because it relates to a different protein. Without acquiescence to the Examiner's characterization of Guo, and solely for the interest of expediting prosecution, claim 1 has been amended without prejudice or disclaimer to recite the claimed process with more specificity. Applicants submit that the claims as amended overcome the rejection for the reasons already of record and for the following additional reasons.

It is noted initially that claim 26, which recited 95% sequence identity to SEQ ID NO: 2 prior to the present amendment, is not included in the present rejection. Since the amended claim 1 incorporates this limitation, it is believed that claim 1, as amended, overcomes this rejection. For the same reason, Applicants believe that new claim 29, which also recites 95% sequence identity to SEQ ID NO: 2, satisfies the requirements under 35 U.S.C. § 112, first paragraph. This is further consistent with the Examiner's statement at page 10 of the Office Action, where the Examiner indicates that the art "teaches how to avoid changes of 5% of the structure of SEQ ID NO: 2." Moreover, Applicants further note that conserved residues between various threonine aldolases are provided, for example, in Figure 1 of the present application. Thus, the requisite guidance is further provided in the specification because, based on the

alignment, one skilled in the art would be able to ascertain where substitutions could or should not be made.

For at least the above reasons and for the reasons already of record, reconsideration and withdrawal of the rejection is respectfully requested in view of the present amendments.

**Rejections under 35 U.S.C. § 102**

Claims 1, 7, 10, 14-16 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Monschau *et al.* (hereinafter “Monschau”).

The Examiner asserts that Monschau teaches a method of producing L-amino acid glycine in a fungal strain *A. gossypii* comprising overexpressing the threonine aldolase gene from *S. cerevisiae*, which is 99.8% identical to SEQ ID NO: 2 and inherently a threonine degrading enzyme. The Examiner further alleges that Monschau teaches expression of a plasmid Yep352, which encodes *GLY1* gene and expressed in YM13, a *S. cerevisiae* strain, citing to page 4288, paragraph 3, lines 11-16, of Monschau. Applicants strongly disagree with the Examiner’s characterization of the Monschau reference and traverse the rejection.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegall Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987). “Rejections under 35 U.S.C. § 102 are proper only when the claimed subject matter is identically disclosed or described in the prior art. Thus, it is not enough that the prior art reference discloses part of the claimed invention, which an ordinary artisan might supplement to make the whole, or that it includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention. The prior art reference must clearly and unequivocally disclose the claimed invention or direct those skilled in the art to the invention without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference.” *Net MoneyIN Inc. v. VeriSign Inc.*, 545 F.3d 1359 (Fed. Cir. 2008) (holding “that unless a reference discloses within the four corners of the document not only all the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.”).

Monschau teaches enhanced riboflavin production in *A. gossypii* by overexpression of the glycine biosynthetic enzyme threonine aldolase. See Monschau at page 4283, Abstract. The *GLY1* gene encoding the threonine aldolase of *A. gossypii* was isolated by heterologous complementation of the glycine-auxotrophic *S. cerevisiae* strain YM13 with a genomic library from *A. gossypii*. *Id.*, see also Monschau at page 4285, paragraph bridging left and right Cols. Throughout the whole disclosure of Monschau, it is the *GLY1* gene of *A. gossypii* that was isolated, characterized, and overexpressed. For instance, as disclosed in “Materials and Methods,” the genomic DNA of *A. gossypii* was isolated and used for the construction of a genomic library, which was then used to perform heterologous complementation of the glycine auxotrophic yeast strain YM13. Monschau at page 4284, left Col., and page 4285, paragraph bridging left and right Cols. Thus, it is clear that the yeast strain YM13 was used as a host for the genomic library of *A. gossypii*. Similarly, it is the *GLY1* gene of *A. gossypii* that was used to construct the *GLY1* overexpression plasmid pAG203*GLY1*, which was subsequently introduced into *A. gossypii* ATCC 10895 for further analysis. Monschau at page 4285, right Col., last paragraph. The only occasion where the *GLY1* gene of *S. cerevisiae* is mentioned is when the deduced amino acid sequence of the *GLY1* gene of *A. gossypii* is compared with that of the *GLY1* gene of *S. cerevisiae*, which according to Monschau, shares 88% similarity. Monschau at page 4285, paragraph bridging left and right Cols. Thus, contrary to the Examiner’s assertion, Monschau does not teach overexpressing the threonine aldolase gene from *S. cerevisiae*.

Furthermore, Applicants note that the *GLY1* gene of *A. gossypii* taught in Monschau shares only 66% sequence identity with SEQ ID NO: 1 of the present application based on ClustalW alignment program using default parameters. Even the deduced amino acid sequence of the *GLY1* gene of *A. gossypii* shares only 75% sequence identity with SEQ ID NO: 2 of the present application. Thus, Monschau also does not teach overexpressing a threonine aldolase gene having 99.8% identity to SEQ ID NO: 2 as alleged by the Examiner, or a nucleotide sequence encoding a polypeptide having at least 95% identity to SEQ ID NO: 2 as recited in the claims.

The Examiner additionally alleges that Monschau teaches harvesting the transgenic microorganism to take the dry weight of the transgenic microorganism, which allegedly reads on isolating the amino acids. Applicants respectfully disagree. It is noted that the claims recites

obtaining the amino acid from the transgenic plant or microorganism. Simply harvesting the transgenic microorganism to take the dry weight of the transgenic microorganism as taught in Monschau is not the same as obtaining the amino acid from the transgenic plant or microorganism.

For at least the above reasons, it is clear that Monschau does not teach each and every element of the claimed process and thus, does not anticipate the claims. Moreover, Applicants further note that Monschau does not teach overexpressing a threonine aldolase gene in a plant as recited in the amended claim 1. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

### **CONCLUSION**

For at least the above reasons, Applicants respectfully request withdrawal of the rejections and allowance of the claims. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Applicants reserve all rights to pursue the non-elected claims and subject matter in one or more divisional applications, if necessary.

Accompanying this response is a petition for a two-month extension of time to and including March 15, 2010 with the required fee authorization. No further fee is believed due. However, if any fee is due, the Director is authorized to charge our Deposit Account No. 03-2775, under Order No. 13195-00006-US from which the undersigned is authorized to draw.

Respectfully submitted,

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